



Quality, innovation and choice

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EC Declaration of Conformity

Intersurgical declares that medical device range described below is in conformity with the essential requirements and provisions of Council Directive 93/42/EEC as amended by 2007/47/EC.

Aerosol, Oxygen and Tracheostomy Mask Products

These are class IIA devices. (classification.doc)

Essential requirements checklist is on IQR139.

Internally manufactured components master data is on EFACS (Parts Master) and design drawings are on IQR69 (Product and Mould Drawing List).

Internally manufactured finished products master data, production drawings and Master Product Formulae are on EFACS (Master Product Formula, Parts Master) and IQR69 (Product and Mould Drawing List).

Externally manufactured materials, components, design drawings and products are on EFACS (Parts Master), IQR98 (Incoming Product Specification) and IQR69 (Product and Mould Drawing List).

Instructions for use, pack inserts and labels are as detailed on EFACS (Master Product Formula) and IQR107 (Index of Controlled Artworks).

Label content is on EFACS (Master Product Formula) and Labels Printing System.

Product realisation processes are referenced in IQM section 7.1

Product Codes

As listed in EFACS MPF Details under group DCAEROXY.DOC.

This range is subject to the procedure set out in Annex 2 excluding section 4 of Directive 93/42/EEC as amended by 2007/47/EC, under the supervision of Notified Body Number 0120, SGS United Kingdom Ltd, Unit 202B, Worle Parkway, Worle Weston Super Mare, Somerset, BS22 6WA, United Kingdom.



Ivan Seniut
Group Quality and Regulatory Affairs Director
Duly authorised for and on behalf of Intersurgical Ltd

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UK • Ireland • France • Germany • Spain • Portugal • Italy
Netherlands • Sweden • Lithuania • Russia • Czech Republic
South Africa • China • Japan • Taiwan • Philippines
USA • Colombia • Australia

Intersurgical Limited Registered in England No. 1488409
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**Intersurgical EC Declaration of Conformity Groups (DC Group) Report
Showing product codes covered by each Declaration of Conformity**

February, 2018

EC Declaration of Conformity Group: DCAEROXY.DOC

DOC 2

Products:

1024081	1101000	1103000	1103002	1103003
1103006	1103007	1103904	1104000	1104001
1105000	1105003	1106000	1107007	1108000
1115000	1115001	1116000	1135000	1135011
1135014	1135015	1135016	1135019	1135020
1135021	1136015	1140000	1141000	1142000
1142015	1143000	1143015	1143016	1145000
1145001	1146000	1148000	1188000	1188004
1188015	1188018	1190000	1190015	1196000
1196010	1196015	1196018	1198000	1198015
1198018	1200000	1200005	1200007	1200050
1206000	1206001	1216000	1216001	

